CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Public Health Protection and Safety
(Amended After Comments)

902 KAR 100:058. Specific licenses to manufacture, assemble, repair, or distribute products.

RELATES TO: KRS 194A.005, 211.842-211.852, 211.990(4), 10 C.F.R. Part 32, 42 U.S.C. 2021(b)~~[31.5, 32.2(b), 32.11, 32.18, 32.19, 32.26, 32.51 - 32.74, 32.101 - 32.103, 32.110, 32.210, 40.34, 40.35, 70.39]~~

STATUTORY AUTHORITY: KRS 13B.170, 194A.050(1), ~~[211.090(3),]~~211.844

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations necessary to implement programs mandated by federal law, to qualify for the receipt of federal funds, and to cooperate with other state and federal agencies. KRS 211.844 requires the cabinet ~~[for Health and Family Services]~~to promulgate administrative regulations concerning the possession or use of sources of ionizing or electronic product radiation and the handling and disposal of radioactive waste. ~~[KRS 194A.050 authorizes the secretary to promulgate administrative regulations necessary to implement programs mandated by federal law or to qualify for the receipt of federal funds and necessary to cooperate with other state and federal agencies for the proper administration of the cabinet and its programs.]~~This administrative regulation establishes requirements for issuing specific licenses to persons who manufacture, assemble, repair, or distribute commodities, products, or devices, that contain radioactive material.

Section 1. Definitions.

(1) "Agreement state" means a state that the United States Nuclear Regulatory Commission (NRC) or the United States Atomic Energy Commission has entered into an effective agreement under subsection 274 b. of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2021(b) et seq.).

(2) "Cabinet" is defined by KRS 194A.005(1).

(3) "Licensee" means a person who holds:

(a) A specific license issued by the cabinet pursuant to 902 KAR 100:185 and this administrative regulation;

(b) A specific licensed issued by the U.S. Nuclear Regulatory Commission or an agreement state; or

(c) A general license pursuant to 902 KAR 100:050 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an agreement state.

Section 2. Applicability. This administrative regulation establishes the requirements for licensees who manufacture or use radioactive material under a general license. Except as established in subsections (1) through (4) of this section, the licensee shall comply with 10 C.F.R. Part 32.

(1) The licensee shall not be subject to:

(a) 10 C.F.R. 32.1(c)(1);

(b) 10 C.F.R. 32.8;

(c) 10 C.F.R. 32.11;

(d) 10 C.F.R. 32.12;

(e) 10 C.F.R. 32.14;

(f) 10 C.F.R. 32.15;

(g) 10 C.F.R. 32.16;

(h) 10 C.F.R. 32.18;
(i) 10 C.F.R. 32.19;
(j) 10 C.F.R. 32.20;
(k) 10 C.F.R. 32.21;
(l) 10 C.F.R. 32.21a;
(m) 10 C.F.R. 32.22;
(n) 10 C.F.R. 32.23;
(o) 10 C.F.R. 32.25;
(p) 10 C.F.R. 32.26;
(q) 10 C.F.R. 32.27;
(r) 10 C.F.R. 32.28;
(s) 10 C.F.R. 32.29;
(t) 10 C.F.R. 32.30;
(u) 10 C.F.R. 32.31;
(v) 10 C.F.R. 32.32;
(w) 10 C.F.R. 32.301; or
(x) 10 C.F.R. 32.303.

(2)

(a) Reference to the NRC, Commission, or an agreement state shall be deemed to reference the Cabinet for Health and Family Services, Department for Public Health, Radiation Health Branch ~~**[, the NRC, or an agreement state]**~~ .

(b) Reference to "Commission" or "agreement state" shall be deemed to be a reference to "Cabinet for Health and Family Services, Department for Public Health, Radiation Health Branch", "Commission", or "agreement state".

(3) Reference to "NRC Form 313, Application for Material License" shall be deemed to be a reference to Form RPS-7, incorporated by reference in 902 KAR 100:040.

(4) Notifications and reports required by 10 C.F.R. Part 32 shall be directed to the manager, Radiation Health Branch at:

(a) 275 East Main Street, Mailstop HS1-C-A, Frankfort, Kentucky 40621;
(b) (502) 564-1492: Facsimile;
(c) (502) 564-3700: Telephone, Monday through Friday, 8 a.m. to 4:30 p.m.; or
(d) (800) 225-2587: Telephone, for hours except those established in paragraph (c) of this subsection. ~~[Registration of Product Information. (1) A manufacturer or initial distributor of a sealed source, or device containing a sealed source, whose product is intended for use under a specific license, shall submit a request to the cabinet pursuant to 10 C.F.R. 32.210, for evaluation of radiation safety information about its product and for its registration.]~~

~~[(2)]~~ ~~[The request for review of a sealed source or device shall include sufficient information to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.]~~

~~[(3)]~~ ~~[The request shall include information on:]~~

~~[(a)]~~ ~~[Design;]~~
~~[(b)]~~ ~~[Manufacture;]~~
~~[(c)]~~ ~~[Prototype testing;]~~
~~[(d)]~~ ~~[Quality control program;]~~
~~[(e)]~~ ~~[Labeling;]~~
~~[(f)]~~ ~~[Proposed uses; and]~~
~~[(g)]~~ ~~[Leak testing.]~~

~~[(4)]~~ ~~[For a device, the request shall also include sufficient information about:]~~

~~[(a)]~~ ~~[Installation;]~~
~~[(b)]~~ ~~[Service and maintenance;]~~
~~[(c)]~~ ~~[Operating and safety instructions; and]~~

[(d)] [Potential hazards.]

[(5)] [The cabinet shall evaluate a sealed source or device using radiation safety criteria in accepted industry standards. If the standards and criteria pursuant to 10 C.F.R. 32.210, do not readily apply to a particular case, the cabinet shall formulate reasonable standards and criteria, with the help of the manufacturer or distributor. The cabinet shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.]

[(6)] [After completion of the evaluation, the cabinet shall issue a certificate of registration to the person making the request. The certificate shall acknowledge the availability of the submitted information for inclusion in an application for a specific license proposing use of the product.]

[(7)] [A person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:]

[(a)] [The statements and representations, including quality control program, contained in the request; and]

[(b)] [The provisions of the registration certificate.]

[Section 2.] [Licensing the Introduction of Radioactive Material into Products in Exempt Concentrations.]

[(1)] [In addition to the requirements established in 902 KAR Chapter 100 a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another, to be transferred to a person exempt under 902 KAR 100:045, Section 2(1)(a) shall be issued if:]

[(a)] [The applicant submits a description of the:]

[1.] [Product or material into which the radioactive material will be introduced;]

[2.] [Intended use of the radioactive material and the product or material into which it is introduced;]

[3.] [Method of introduction;]

[4.] [Initial concentration of the radioactive material in the product or material;]

[5.] [Control methods to assure that no more than the specified concentration shall be introduced into the product or material;]

[6.] [Estimated time interval between introduction and transfer of the product or material; and]

[7.] [Estimated concentrations of the radioactive material in the product or material at the time of transfer; and]

[(b)] [The applicant provides reasonable assurance that the:]

[1.] [Concentrations of the radioactive material at the time of transfer shall not exceed the concentrations established in 902 KAR 100:085;]

[2.] [Reconcentration of the radioactive material in concentrations exceeding those in 902 KAR 100:085 is not likely;]

[3.] [Use of lower concentrations is not feasible; and]

[4.] [Product or material is not likely to be incorporated in a food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.]

[(2)] [A person licensed pursuant to this administrative regulation shall:]

[(a)] [Maintain records of transfer of radioactive material;]

[(b)] [File an annual report with the cabinet that shall include the:]

[1.] [Type and quantity of a product or material into which radioactive material has been introduced during the reporting period;]

[2.] [Name and address of the person who owned or possessed the product or material into which radioactive material has been introduced at introduction;]

[3.] [Type and quantity of radionuclide introduced into a product or material; and]

[4.] [Initial concentrations of the radionuclide in the product or material at transfer of the radioactive material by the licensee;]

[(c)] [Indicate in the report if no transfers of radioactive material have been made during the reporting period;]

[(d)] [File a report by July 30 covering the year ending the previous June 30; and]

[(e)] [Maintain the record of a transfer for a period of one (1) year after the event is included in a report to the cabinet.]

[Section 3.] [Resins Containing Scandium-46 and Designed for Sand-Consolidation in Oil Wells: Requirements for License to Manufacture or Initially Transfer for Sale or Distribution. An application for a specific license to manufacture or initially transfer for sale or distribution, synthetic plastic resins containing scandium-46 for use as indicated in 902 KAR 100:045, Section 3(3), shall be approved if:]

[(1)] [The applicant satisfies the requirements specified in 902 KAR 100:040, Section 4;]

[(2)] [The product is designed to be used only for sand-consolidation in oil wells;]

[(3)] [The applicant submits the following information:]

[(a)] [A general description of the product to be manufactured or initially transferred; and]

[(b)] [A description of control procedures used to assure that the concentration of scandium-46 in the final product at the time of distribution shall not exceed $1.4x10^{-3}$ micro-curie/milliliter; and]

[(4)] [A container of the product bears a durable, legible label approved by the cabinet based on the following information:]

[(a)] [The product name;]

[(b)] [A statement that the product contains radioactive scandium and is designed and manufactured only for sand-consolidation in oil wells;]

[(c)] [Instructions necessary for proper use; and]

[(d)] [The manufacturer's name.]

[Section 4.] [Licensing the Manufacture and Distribution of a Device to a Person Generally Licensed under 902 KAR 100:050.]

[(1)] [In addition to the requirements established in 902 KAR Chapter 100 an application for a specific license to distribute certain devices containing radioactive material, excluding special nuclear material, to a person generally licensed shall be issued only if the applicant submits sufficient information relating to the:]

[(a)] [Design;]

[(b)] [Manufacture;]

[(c)] [Prototype testing;]

[(d)] [Quality control;]

[(e)] [Labels;]

[(f)] [Proposed uses;]

[(g)] [Installation;]

[(h)] [Servicing;]

[(i)] [Leak testing;]

[(j)] [Operating and safety instructions; and]

[(k)] [Potential hazards of the device to provide reasonable assurance that:]

[1.] [Under accident conditions, such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that a person would receive an external radiation dose or dose commitment in excess of the following organ doses:]

[a.] [Whole body, head and trunk, active blood-forming organs, gonads, or lens of eye – 15 rems (150 mSv);]

[b.] [Hands and forearms, feet and ankles, or localized areas of skin averaged over areas no larger than one (1) square centimeter - 200 rems (2 Sv); or]

[c.] [Other organs - 50 rems (500 mSv);]

[2.] [Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device shall not be released or inadvertently removed from the device, and it is unlikely that a person will receive in a period of one (1) calendar year a dose in excess of ten (10) percent of the limits specified in 902 KAR 100:019, Section 3; and]

[3.] [The device can be safely operated by individuals not having training in radiological protection.]

[(2)] [A device identified in subsection (1) of this section shall bear a durable, legible, clearly visible label or labels, in accordance with 902 KAR 100:050, which contain in a clearly identified and separate statement:]

[(a)] [Instructions and precautions necessary to assure safe installation, operation, and servicing of the device or reference to documents, such as operating and service manuals identified in the label that are used to provide this information;]

[(b)] [The requirement, or lack of requirement, for leak testing or for testing an "on-off" mechanism and indicator, including the maximum time interval for the testing and the identification of radioactive material by:]

[1.] [Isotope;]

[2.] [Quantity of radioactivity; and]

[3.] [Date of determination of the quantity; and]

[(c)] [The information called for in the following statement, in the same or substantially similar form: "The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited. CAUTION – RADIOACTIVE MATERIAL Name of manufacturer or distributor The model, serial number, and name of the manufacturer or distributor may be omitted from this label if the information is elsewhere specified in labeling affixed to the device.]

[(3)]

[(a)] [If the applicant desires that the device identified in subsection (1) of this section be required to be tested for proper operation of the "on-off" mechanism and indicator or for leakage of radioactive material, subsequent to the initial tests required by this administrative regulation at intervals longer than six (6) months but not exceeding three (3) years, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by:]

[1.] [Performance characteristics of the device or similar devices; and]

[2.] [Design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator.]

[(b)] [In determining the acceptable interval for the test for leakage of radioactive material, the cabinet may consider information that shall include:]

[1.] [Primary containment or source capsule;]

[2.] [Protection of primary containment;]

[3.] [Method of sealing containment;]

[4.] [Containment construction materials;]

[5.] [Form of contained radioactive material;]

[6.] [Maximum temperature withstood during prototype tests;]

[7.] [Maximum pressure withstood during prototype tests;]

[8.] [Maximum quantity of contained radioactive material;]

[9.] [Radiotoxicity of contained radioactive material; and]

[10.] [Operating experience with identical devices or similarly designed and constructed devices.]

[(4)]

[(a)] [If the applicant desires authorization of the general licensee established in 902 KAR 100:050, Section 3, or pursuant to equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application:]

[1.] [Written instructions to be followed by the general licensee;]

[2.] [Estimated calendar quarter doses associated with the activity or activities; and]

[3.] [Basis for the estimates.]

[(b)] [The information shall demonstrate that performance of the activity by an individual untrained in radiological protection, handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of ten (10) percent of the annual limits specified in 902 KAR 100:019, Section 3.]

[(5)] [A person licensed pursuant to this administrative regulation to distribute devices to generally licensed persons shall:]

[(a)] [Furnish a copy of the general license identified in 902 KAR 100:050, Section 3, to each person to whom the licensee, directly or through an intermediate person, transfers radioactive material in a device for use as authorized by a general license;]

[(b)] [Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to 902 KAR 100:050, Section 3, or alternatively, furnish a copy of the general license to each person to whom the licensee directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or the Agreement State. If a copy of the general license identified in 902 KAR 100:050, Section 3, is furnished to the person, it shall be accompanied by a note explaining that the use of the device is regulated by the U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in 902 KAR 100:050, Section 3;]

[(c)] [Report to the cabinet transfers of the devices to persons for use under the general license.]

[1.] [The report shall identify:]

[a.] [A general licensee by name and address;]

[b.] [An individual by name or position who may constitute a point of contact between the cabinet and the general licensee;]

[c.] [The type and model number of device transferred; and]

[d.] [The quantity and type of radioactive material contained in the device].

[2.] [If one (1) or more intermediate persons possess the device temporarily at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user.]

[3.] [The report shall indicate if no transfers have been made to persons generally licensed during the reporting period.]

[4.] [The report shall cover a calendar quarter and shall be filed within thirty (30) days of the close of the quarter.]

[(d)] [Furnish reports to other agencies, including:]

[1.]

[a.] [Report to the U.S. Nuclear Regulatory Commission transfers of these devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 31.5 of 10 C.F.R. Part 31; or]

[b.] [Report to the responsible state agency transfers of devices manufactured and distributed for use under a general license in that state's regulations equivalent to 902 KAR 100:050, Section 3;]

[c.] [Identify:]

[(i)] [A general licensee by name and address;]

[(ii)] [An individual by name or position who may constitute a point of contact between the agency and the general licensee;]

[(iii)] [The type and model of the device transferred; and]

[(iv)] [The quantity and type of radioactive material contained in the device;]

[2.] [If one (1) or more intermediate persons possess the device temporarily at the intended place of use prior to its possession by the user, include identification of each intermediate person by name, address, contact, and relationship to the intended user;]

[3.] [Submit within thirty (30) days after the end of the calendar quarter in which the device is transferred to the generally licensed person;]

[4.] [If no transfers have been made to U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission; and]

[5.] [If no transfers have been made to general licensees within a particular state during the reporting period, this information shall be reported to the responsible state agency upon request of that agency;]

[(e)] [Keep records showing the name, address, and the point of contact for a general licensee to which the licensee, directly or through an intermediate person, transfers radioactive material in devices for use as authorized by a general license or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall show:]

[1.] [The date of transfer;]

[2.] [The radionuclide and the quantity of radioactivity in each device transferred;]

[3.] [The identity of the intermediate person; and]

[4.] [Compliance with the report requirements; and]

[(f)] [Maintain the records required by paragraphs (c) and (d) of this subsection for a period of five (5) years from the date of the recorded transfer.]

[Section 5.] [Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed pursuant to 902 KAR 100:050, shall be approved if:]

[(1)] [The applicant satisfies the requirements specified in 902 KAR 100:040, Section 4; and]

[(2)] [The applicant satisfies the requirements of U.S. Nuclear Regulatory Commission 10 C.F.R. Part 32, Sections 32.2(b), 32.53, 32.54, 32.55, 32.56, 32.101, and 32.110 or their equivalent.]

[Section 6.] [Special Requirements for License to Manufacture and Distribute Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Licensed pursuant to 902 KAR 100:050. An application for a specific license to manufacture or distribute calibration and reference sources containing americium-241, plutonium or radium-226 to persons generally licensed pursuant to 902 KAR 100:050 shall be approved if:]

[(1)] [The applicant satisfies the requirements established in 902 KAR 100:040, Section 4; and]

[(2)] [The applicant satisfies the requirements of U.S. Nuclear Regulatory Commission 10 C.F.R. Part 32, Sections 32.57, 32.58, 32.59, and 32.102, and 10 C.F.R. Part 70, Section 70.39, or their equivalent.]

[Section 7.] [Licensing the Manufacture and Distribution of Ice Detection Devices Containing Strontium-90. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed shall be approved if:]

[(1)] [The applicant satisfies the requirements established in 902 KAR 100:040, Section 4; and]

[(2)] [The criteria of U.S. Nuclear Regulatory Commission 10 C.F.R. Part 32, Sections 32.2(b), 32.61, 32.62, 32.103, and 32.110 are met.]

[Section 8.] [Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing under a General License. An application for a specific license to manufacture or distribute radioactive material for use pursuant to the general license established in 902 KAR 100:050, Section 4, shall be approved if:]

[(1)] [The applicant satisfies the general requirements specified in 902 KAR 100:040, Section 4;]

[(2)] [The radioactive material is to be prepared for distribution in prepackaged units of:]

[(a)] [Iodine-125 in units not exceeding ten (10) microcuries (370 kBq) each;]

[(b)] [Iodine-131 in units not exceeding ten (10) microcuries (370 kBq) each;]

[(c)] [Carbon-14 in units not exceeding ten (10) microcuries (370 kBq) each;]

[(d)] [Hydrogen-3 (tritium) in units not exceeding fifty (50) microcuries (1.85 MBq) each;]

[(e)] [Iron-59 in units not exceeding twenty (20) microcuries (704 kBq) each;]

[(f)] [Selenium-75 in units not exceeding ten (10) microcuries (370 kBq) each;]

[(g)] [Mock iodine-125 in units not exceeding 0.05 microcurie (1.85 MBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; or]

[(h)] [Cobalt-57 in units not exceeding fifty (50) microcuries (370 kBq) each;]

[(3)] [Each prepackaged unit bears a durable, clearly visible label:]

[(a)] [Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed:]

[1.] [Ten (10) microcuries (370 kBq) of iodine-131, iodine-125, selenium-75, cobalt-57, or carbon-14;]

[2.] [Fifty (50) microcuries (1.85 MBq) of hydrogen-3 (tritium);]

[3.] [Twenty (20) microcuries (740 kBq) of iron-59; or]

[4.] [Mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; and]

[(b)] [Displaying the radiation caution symbol described in 902 KAR 100:019, Section 23, and the words, "Caution, Radioactive Material" and "Not for Internal or External Use in Humans or Animals";]

[(4)] [The following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to a prepackaged unit, or appears in a leaflet or brochure which accompanies the package: "This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the administrative regulations and a general license or the equivalent of the United States Nuclear Commission or of an Agreement State. (Name of Manufacturer)"; and]

[(5)] [The label affixed to the unit, or the leaflet or brochure that accompanies the package, contains adequate information regarding precautions to be observed in handling and storing the radioactive material. For a mock iodine-125 reference or calibration source, the information accompanying the source shall contain directions to the licensee regarding the waste disposal requirements established in 902 KAR 100:021, Section 1.]

[Section 9.] [Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Specific Licenses.]

[(1)] [An application for a specific license to manufacture, prepare, or transfer for commercial distribution radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to 902 KAR 100:072, shall be approved if the applicant:]

[(a)] [Satisfies the requirements specified in 902 KAR 100:040, Section 4;]

[(b)] [Submits evidence that the applicant is at least one (1) of the following:]

[1.] [Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer;]

[2.] [Registered or licensed with a state agency as a drug manufacturer;]

[3.] [Licensed as a pharmacy by the State Board of Pharmacy; or]

[4.] [Operating as a nuclear pharmacy within the federal medical institution;]

[(c)] [Submits information on:]

[1.] [The radionuclide;]

[2.] [Chemical and physical form;]

[3.] [Maximum activity per vial, syringe, generator, or other container of the radioactive drug; and]

[4.] [Shielding provided by the packaging of the radioactive material to show it is appropriate for safe handling and storage of radiopharmaceuticals by medical use licensees; and]

[(d)] [Satisfies the labeling requirements in this paragraph:]

[1.] [The label shall be affixed to the transport radiation shield, if it is constructed of lead, glass, plastic, or other material of a radioactive drug to be transferred for commercial distribution. The label shall include:]

[a.] [The radiation symbol;]

[b.] [The words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL";]

[c.] [The name of the radioactive drug or its abbreviation; and]

[d.] [The quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.]

[2.] [A label shall be affixed to a syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include:]

[a.] [The radiation symbol;]

[b.] [The words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; and]

[c.] [An identifier that ensures the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.]

[(2)] [A licensee described by subsection (1)(b)3 or 4 of this section may:]

[(a)] [Prepare radioactive drugs for medical use, as defined in 902 KAR 100:010, if the radioactive drug is prepared by an authorized nuclear pharmacist, as specified in paragraphs (b) and (c) of this subsection, or an individual under the supervision of an authorized nuclear pharmacist, as specified in 902 KAR 100:072, Section 12;]

[(b)] [Allow a pharmacist to work as an authorized nuclear pharmacist if the individual:]

[1.] [Qualifies as an authorized nuclear pharmacist as defined in 902 KAR 100:010;]

[2.] [Meets the requirements specified in 902 KAR 100:072, Sections 63 and 66, and the licensee has received an approved license amendment identifying the individual as an authorized nuclear pharmacist; or]

[3.] [Is designated as an authorized nuclear pharmacist in accordance with paragraph (c) of this subsection; and]

[(c)] [Designate a pharmacist as an authorized nuclear pharmacist if the individual is identified as an authorized user on a nuclear pharmacy license issued by the cabinet.]

[(3)] [The actions authorized in subsections (2)(a) and (b) of this section shall be permitted in spite of more restrictive language in license conditions.]

[(4)] [A licensee shall provide to the cabinet a copy of an individual's certification by the Board of Pharmaceutical Specialties, the cabinet, the U.S. Nuclear Regulatory Commission, or an agreement state license, and a copy of the state pharmacy licensure or registration, no later than thirty (30) days after the date that the licensee allows the individual to work as an authorized nuclear pharmacist, pursuant to subsection (2)(b)1 and 3 of this section.]

[(5)] [A licensee shall:]

[(a)] [Possess and use instrumentation to measure the radioactivity of radioactive drugs;]

[(b)] [Have procedures for use of the instrumentation;]

[(c)] [Measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta- or photon-emitting radioactive drugs prior to transfer for commercial distribution;]

[(d)] [Perform accuracy, linearity, and geometry dependence tests on an instrument before initial use, periodically, and following repair, as appropriate for the instrument, and make necessary adjustments; and]

[(e)] [Check an instrument for constancy and proper operation at the beginning of each day of use.]

[(6)] [This section shall not relieve a licensee from complying with applicable FDA, other federal, and state requirements governing radioactive drugs.]

[Section 10.] [Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed as authorized by 902 KAR 100:072 for use as a calibration, transmission, or reference source or for medical uses listed in 902 KAR 100:072, Sections 37, 45 and 46 shall be approved if:]

[(1)] [The applicant satisfies the requirements established in 902 KAR 100:040, Section 4;]

[(2)] [The applicant submits sufficient information regarding a type of source or device pertinent to an evaluation of its radiation safety, including:]

[(a)] [The radioactive material contained, its chemical and physical form, and amount;]

[(b)] [Details of design and construction of the source or device;]

[(c)] [Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;]

[(d)] [For devices containing radioactive material, the radiation profile of a prototype device;]

[(e)] [Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;]

[(f)] [Procedures and standards for calibrating sources and devices;]

[(g)] [Legend and methods for labeling sources and devices as to their radioactive content; and]

[(h)] [Instructions for handling and storing the source or device from the radiation safety standpoint. The instructions shall be included on a durable label attached to the source or device, or attached to a permanent storage container for the source or device. Instructions too lengthy for a label may be summarized on the label and printed in detail on a brochure referenced on the label;]

[(3)] [The label affixed to the source or device, or to the permanent storage container for the source or device, contains:]

[(a)] [Information on the radionuclide;]

[(b)] [Quantity and date of assay; and]

[(c)] [A statement that the name of source or device is licensed by the cabinet for distribution to persons licensed as authorized by 902 KAR 100:072, or under equivalent licenses of the U.S. Nuclear Regulatory Commission or an Agreement State;]

[(4)] [If an applicant desires the source or device to be tested for leakage of radioactive material at intervals longer than six (6) months, the applicant shall include in the application sufficient information to demonstrate that the longer interval is justified by:]

[(a)] [Performance characteristics of the source or device, or similar sources or devices; and]

[(b)] [Design features having a significant bearing on the probability or consequence of leakage of radioactive material from the source; and]

[(5)] [In determining the acceptable interval for tests of leakage of radioactive material, the cabinet shall consider information that includes:]

[(a)] [Primary containment or source capsule;]

[(b)] [Protection of primary containment;]

[(c)] [Method of sealing containment;]

[(d)] [Containment construction materials;]

[(e)] [Form of contained radioactive material;]

[(f)] [Maximum temperature withstood during prototype tests;]

[(g)] [Maximum pressure withstood during prototype tests;]

[(h)] [Maximum quantity of contained radioactive material;]

[(i)] [Radiotoxicity of contained radioactive material; and]

[(j)] [Operating experience with identical sources or devices, or similarly designed and constructed sources or devices.]

[Section 11.] [Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-volume Applications.]

[(1)] [An application for a specific license to manufacture or distribute an industrial product or device containing depleted uranium for use authorized by 902 KAR 100:050, Section 2, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State shall be approved if:]

[(a)] [The applicant satisfies the general requirements specified in 902 KAR 100:040, Section 4;]

[(b)] [The applicant submits sufficient information relating to the:]

[1.] [Design;]

[2.] [Manufacture;]

[3.] [Prototype testing;]

[4.] [Quality control procedures;]

[5.] [Labeling or marking;]

[6.] [Proposed uses; and]

[7.] [Potential hazards of the industrial product or device;]

[(c)] [The applicant provides reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause an individual to

receive in a period of one (1) year a radiation dose in excess of ten (10) percent of the limits specified in 902 KAR 100:019, Section 3; and]

[(d)] [The applicant submits sufficient information regarding the industrial product or device, and the presence of depleted uranium for a mass-volume application in the product or device, to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.]

[(2)] [For an industrial product or device that has questionable unique benefits, the cabinet may approve an application for a specific license pursuant to this section only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.]

[(3)] [The cabinet shall deny an application for a specific license pursuant to this section if the end use of the industrial product or device cannot reasonably be foreseen.]

[(4)] [A person licensed as authorized by this section shall:]

[(a)] [Maintain the level of quality control required by the license in:]

[1.] [Manufacture of the industrial product or device; and]

[2.] [Installation of the depleted uranium into the product or device;]

[(b)] [Label or mark each unit to identify:]

[1.] [The manufacturer of the product or device;]

[2.] [The number of the license under which the product or device was manufactured or distributed;]

[3.] [The fact that the product or device contains depleted uranium;]

[4.] [The quantity of depleted uranium in the product or device; and]

[5.] [That the receipt, possession, use, or transfer of the product or device is subject to a general license, or the equivalent, and the regulations of the U.S. Nuclear Regulatory Commission or an Agreement State;]

[(c)] [Assure that the depleted uranium, before being installed in a product or device, has been impressed with the legend "DEPLETED URANIUM" clearly legible through plating or other covering;]

[(d)] [Furnish a copy of the general license contained in:]

[1.] [902 KAR 100:050 to a person to whom depleted uranium is transferred in a product or device for use authorized by the general license; or]

[2.] [The U.S. Nuclear Regulatory Commission's or Agreement State's regulation equivalent to 902 KAR 100:050, and a copy of an applicable U.S. Nuclear Regulatory Commission's or Agreement State's certificate, to a person to whom depleted uranium is transferred in a product or device for use as authorized by the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in 902 KAR 100:050;]

[(e)] [Furnish the following to either the cabinet, U.S. Nuclear Regulatory Commission, or agreement state:]

[1.] [A report of each transfer of an industrial product or device to a person for use pursuant to the general license in 902 KAR 100:050. The report shall identify:]

[a.] [A general licensee by name and address;]

[b.] [An individual, by name or position, who constitutes a point of contact between the cabinet and the general licensee;]

[c.] [The type and model number of device transferred; and]

[d.] [The quantity of depleted uranium contained in the product or device.]

[2.] [The report identified in subparagraph 1 of this paragraph shall be submitted within thirty (30) days after the end of a calendar quarter in which the product or device is transferred to the generally licensed person. If no transfers have been made

to persons generally licensed pursuant to 902 KAR 100:050 during the reporting period, the report shall so indicate; and]

[(f)] [Keep records showing the name, address, and point of contact for a general licensee to whom he transfers depleted uranium in an industrial product or device for use authorized by the general license provided in 902 KAR 100:050 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. The records shall be maintained for a period of three (3) years from the date of transfer and shall show the date of each transfer, the quantity of depleted uranium in a product or device transferred, and compliance with the report requirements of this section.]

[Section 12.] [Licensing the Distribution of Naturally Occurring and Accelerator Produced Radioactive Material (NARM) in Exempt Quantities.]

[(1)] [An application for a specific license to distribute NARM to persons exempted from these regulations authorized by 902 KAR 100:045 shall be approved if:]

[(a)] [The radioactive material is not contained in a food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;]

[(b)] [The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into a manufactured or assembled commodity, product, or device intended for commercial distribution; and]

[(c)] [The applicant submits copies of prototype labels and brochures in accordance with 10 C.F.R. 32.18 and 32.19 and the cabinet approves the labels and brochures.]

[(2)] [The license issued pursuant to this section shall be subject to the following conditions:]

[(a)] [More than ten (10) exempt quantities shall not be sold or transferred in a single transaction. However, an exempt quantity may be composed of fractional parts of one (1) or more of the exempt quantity, if the sum of the fractions does not exceed unity.]

[(b)] [An exempt quantity shall be packaged separately and individually. More than ten (10) packaged exempt quantities shall not be contained in an outer package for transfer to persons exempt as authorized by 902 KAR 100:045. The dose rate at the external surface of the outer package shall not exceed five-tenths (0.5) millirem per hour.]

[(c)] [The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:]

[1.] [Identifies the radionuclide and the quantity of radioactivity; and]

[2.] [Bears the words "Radioactive Material."]

[(d)] [In addition to the labeling information required by this subsection, the label affixed to the immediate container, or an accompanying brochure, shall:]

[1.] [State that the contents are exempt from licensing agency requirements;]

[2.] [Bear the words "Radioactive Material - Not for Human Use - Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited - Exempt Quantities Should Not Be Combined"; and]

[3.] [Establish appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.]

[(3)]

[(a)] [A person licensed pursuant to this section shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use in accordance with 902 KAR 100:045 or the equivalent regulations of a licensing agency, and stating the kinds and quantities of radioactive material transferred.]

[(b)] [An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the cabinet.]

[(c)] [A report shall cover the year ending June 30 and shall be filed within thirty (30) days after June 30. The report shall indicate if no transfers of radioactive material have been made during the reporting period, as authorized by this section.]

[Section 13.] [Licensing the Incorporation of Naturally Occurring and Accelerator Produced Radioactive Material (NARM) into Gas and Aerosol Detectors.]

[(1)] [An application for a specific license authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt pursuant to 902 KAR 100:045 shall be approved if the application satisfies requirements equivalent to those contained in U.S. Nuclear Regulatory Commission 10 C.F.R. Part 32.26.]

[(2)] [The maximum quantity of radium-226 in a device shall not exceed one-tenth (0.1) microcurie (3.7 kBq).]

(1 Ky.R. 396; eff. 2-5-1975; Am. 12 Ky.R. 1020; eff. 1-3-1986; 13 Ky.R. 1766; eff. 5-14-1987; 18 Ky.R. 1510; eff. 1-10-1992; 26 Ky.R. 2395; 27 Ky.R. 970; eff. 10-16-2000; 37 Ky.R. 1820; 2612; eff. 6-3-2011; 41 Ky.R. 907; 1601; eff. 2-5-2015; Cert. eff. 11-12-2021; 50 Ky.R. 205, 1147; eff. 12-13-2023.)

STEVEN J. STACK, Commissioner
ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: September 27, 2023

FILED WITH LRC: October 12, 2023 at 9:30 a.m.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Krista Quarles or Julie Brooks

(1) Provide a brief summary of:

(a) What this administrative regulation does:
This administrative regulation establishes requirements for issuing specific licenses to persons who manufacture, assemble, repair, or distribute commodities, products, or devices, that contain radioactive material.

(b) The necessity of this administrative regulation:
This administrative regulation is necessary to protect radiation workers and the public from exposure to excessive radiation and set safety limits.

(c) How this administrative regulation conforms to the content of the authorizing statutes:
KRS 211.844 requires the cabinet to provide by administrative regulation the requirements for the licensing, use, and disposal of radioactive materials.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:
This administrative regulation ensures all those engaged in the licensing, use, transfer, and disposal of radioactive source material meet the regulatory requirements.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:
The amendment to this administrative regulation adopts by reference the applicable requirements of 10 C.F.R. Part 32. The amended after comments version makes changes to section 2(2) for clarity on references to the department, the commission, or an agreement state.

(b) The necessity of the amendment to this administrative regulation:
As an agreement state with the Nuclear Regulatory Commission (NRC), the Radiation Health Branch (RHB) is required to have state regulations compatible with the regulations promulgated by NRC.

(c) How the amendment conforms to the content of the authorizing statutes:
KRS 211.842(1) and (2) establish the cabinet as the radiation control agency of Kentucky and authorize the cabinet to issue licenses pertaining to radioactive materials and require registration of other sources of ionizing radiation.

(d) How the amendment will assist in the effective administration of the statutes:
The amendment to this administrative regulation ensures all licensees who have a specific license to manufacture, assemble, repair, or distribute commodities, products, or devices, that contain radioactive material are in full compliance with both state and federal requirements.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:
There are currently 118 licenses issued for certain uses of radioactive material and specific devices containing radioactive material.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:

The RHB will need to revise guidance documents for licensees to reflect these changes. No additional actions will be needed by the licensee to comply with this administrative regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

There is a minimal cost to the cabinet associated with updating guidance documents.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

Adopting the applicable parts of10 C.F.R. Part 32 will reduce the redundancy between state and federal requirements. This will reduce the time needed to research applicable regulations and make it easier for the licensee to review existing guidance documents.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

This is an ongoing program, there are no initial costs.

(b) On a continuing basis:

This administrative regulation does not impact cost.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

The Radiation Health Branch is funded through a mix of state general fund dollars and the various fees associated with issuing licenses.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

An increase in fees or funding is not needed to implement the amendment to this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

There are no fees associated with this administrative regulation.

(9) TIERING: Is tiering applied?

Tiering is not applied. The requirements of this administrative regulation are applied equally to all licensees.

FISCAL NOTE

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

The Radiation Health Branch within the Department for Public Health will be impacted by this administrative regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 194A.050(1) and 211.844.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

This administrative regulation does not generate revenue.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

This administrative regulation does not generate revenue.

(c) How much will it cost to administer this program for the first year?

This administrative regulation does not add cost to the agency.

(d) How much will it cost to administer this program for subsequent years?

This administrative regulation does not add cost to the agency.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

This administrative regulation may result in minimal cost savings for the regulated entities. The amendment to this administrative regulation reduces the administrative burden of having to research and follow duplicative state and federal requirements.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

This administrative regulation may result in minimal cost savings for the regulated entities. The amendment to this administrative regulation reduces the administrative burden of having to research and follow duplicative state and federal requirements.

(c) How much will it cost the regulated entities for the first year?

This administrative regulation will have no impact on cost for the regulated entities.

(d) How much will it cost the regulated entities for subsequent years?

This administrative regulation will have no impact on cost for the regulated entities.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-):

Expenditures (+/-):

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.

"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] This administrative regulation does not have a major economic impact.

FEDERAL MANDATE ANALYSIS COMPARISON

(1) Federal statute or regulation constituting the federal mandate.

Atomic Energy Act of 1954, 42 U.S.C. 2021, as amended, and 10 C.F.R. Part 32.

(2) State compliance standards.

As an agreement state with the Nuclear Regulatory Commission, the state is required to have a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the state covered by the proposed agreement. The state is required to adopt compliance standards for the protection of the public health, safety, and environment from hazards associated with such material which are equivalent, to the extent practicable, or more stringent than, standards adopted and enforced by the Commission for the same purpose.

(3) Minimum or uniform standards contained in the federal mandate.

In accordance with 42 U.S.C. 2021(g), the Commission is authorized and directed to cooperate with the states in the formulation of standards for protection against hazards of radiation to assure that state and Commission programs for protection against hazards of radiation will be coordinated and compatible. Pursuant to 42 U.S.C. 2021(a)(3), the purpose of this standard is to promote orderly regulatory pattern between the commission and state governments with respect to nuclear development and use and regulation of byproduct, source, and special nuclear materials.

(4) Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?

No

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.

Not applicable as there are no stricter standards, or additional or different responsibilities or requirements.